K040895

MAY 21 2004

510(k) SUMMARY

NAME & ADDRESS: DENTSPLY International
World Headquarters
Susquehanna Commerce Ctr.
221 West Philadelphia Street
York, PA 17405-0872
(717) 845-7511 (voice)
~~(717) 849-4762 (fax)~~
www.dentsply.com

P. J. Lehn Telefax (717) 849-4343

CONTACT: P. Jeffery Lehn

DATE PREPARED: March 30, 2004

TRADE OR PROPRIETARY NAME: INTEGRITY™ TEMPORARY CEMENT

CLASSIFICATION NAME: Dental cement (872.3275)

PREDICATE DEVICES: BIOMER™ Composite Luting Cement (K853431)
T.E.R.M.™ VLC Temporary Endo Restorative Material (K854253)

DEVICE DESCRIPTION: INTEGRITY™ TEMPORARY CEMENT is a dual-cured or self-cured temporary resin cement for use with provisional crown and bridge restorations. The cement is dispensed from a dual barrel 5 ml syringe for hand-mixing on a mix pad or for use with an automix tip. It is then polymerized by dual curing. Visible light initiators are used for self-curing.

INTENDED USE: INTEGRITY™ TEMPORARY CEMENT is indicated for: 1) temporary cementation of provisional acrylic and composite indirect restorations to prepared teeth or implant abutments; 2) provisional or trial cementation of ceramic, porcelain, composite, PFM (porcelain fused to metal) and all metal crowns and bridges to prepared teeth or implant abutments; and 3) cementation of ceramic, porcelain, composite, PFM (porcelain fused to metal) and all metal crowns and bridges to implant abutments and telescopic fixed restorations which require periodic removal for maintenance, etc.

TECHNOLOGICAL CHARACTERISTICS: All of the components found in INTEGRITY™ TEMPORARY CEMENT have been used in legally marketed devices or were found safe for dental use. INTEGRITY™ TEMPORARY CEMENT has been evaluated and passed biocompatibility testing for cytotoxicity, acute oral toxicity, mutagenicity, irritation and sensitization.

We believe that the prior use of the components of INTEGRITY™ TEMPORARY CEMENT in legally marketed devices, the performance data provided, and the biocompatibility data provided support the safety and effectiveness of INTEGRITY™ TEMPORARY CEMENT for the indicated uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 21 2004

Dentsply International
Mr. P Jeffery Lehn
Director of Corporate Compliance and Regulatory Affairs
Susqehanna Commerce Center West
221 West Philadelphia Street
York, Pennsylvania 17405-0872

Re: K040895
Trade/Device Name: INTEGRITY™ TEMPORARY CEMENT
Regulation Number: 872.3760
Regulation Name: Denture Relining Repairing or Rebasing Resin
Regulatory Class: II
Product Code: EMA
Dated: March 30, 2004
Received: April 6, 2004

Dear Mr. Lehn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

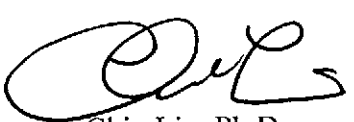
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

(As Required by 21 CFR 807.87(e)

510(K) Number (if known): K040895

Device Name: **INTEGRITY™ TEMPORARY CEMENT**

Indications for Use:

INTEGRITY™ TEMPORARY CEMENT is indicated for:

1. Temporary cementation of provisional acrylic and composite indirect restorations to prepared teeth or implant abutments.
2. Provisional or trial cementation of ceramic, porcelain, composite, PFM (porcelain fused to metal) and all metal crowns and bridges to prepared teeth or implant abutments.
3. Cementation of ceramic, porcelain, composite, PFM (porcelain fused to metal) and all metal crowns and bridges to implant abutments and telescopic fixed restorations which require periodic removal for maintenance, etc.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sora Reaves

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K040895